ASSESSMENT OF THE POTENTIAL RISKS TO HOMEOWNERS AND RESIDENTIAL CONTRACTORS FROM ASBESTOS EXPOSURE ASSOCIATED WITH VERMICULITE ATTIC INSULATION

REPORT BY:
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QUALIFICATIONS

1. I am the President and Chief Executive Officer of Sciences International, Inc., a company of scientists dedicated to health and environmental assessment.

2. I have a Ph.D. in organic chemistry and am a Fellow of the Academy of Toxicological Sciences. Formerly, I spent 14 years at the U.S. Environmental Protection Agency (EPA), from October 1971 to December 1985, where I directed EPA's central risk assessment programs for the last 10 years of my tenure. Specifically, in 1975, I became the Executive Director of an intra-Agency committee that was commissioned to write an Agency cancer policy. This committee developed the Agency's first risk assessment guidelines for assessing risk associated with exposure to suspected carcinogens in the environment. Subsequently, in 1976, I established EPA's first Carcinogen Assessment Group (CAG) which formed the core for the enlarged office, the Office of Health and Environmental Assessment (OHEA), now called the National Center for Environmental Assessment, which was established in 1978. As the director of the first CAG and then OHEA, I had responsibility for the central risk assessment activities of EPA for 10 years before I left the Agency. The primary functions of this office were to conduct assessments and establish the toxicity of a wide variety of toxic agents, provide leadership to establish EPA-wide guidelines for toxicity and risk assessments, and oversee EPA's health assessment programs. Of particular relevance to the issues herein addressed, my office was responsible for the risk assessment of toxic air pollutants and for writing the National Ambient Air Quality Criteria Documents. During my tenure as the director of OHEA, I was

responsible for the draft document, Airborne Asbestos Health Assessment Update (EPA, 1986), which was published in June 1986, shortly after my departure.

3. Since leaving EPA, I have continued active participation in the sciences of health and environmental risk assessment. For example, I am past-President of the Society for Risk Analysis; and am currently Editor-in-Chief of the journal, *Risk Analysis: An International Journal*, which is the leading peer-reviewed international journal on topics of risk assessment. I regularly serve on expert peer review and advisory committees on risk assessment topics for the EPA and other organizations including current appointments to the Department of Energy's Los Alamos National Laboratory Expert Advisory Committee, a recent expert committee for the National Academy of Sciences, and an EPA expert committee that is exploring ways to improve EPA's repository of toxicological and risk information called the Integrated Risk Information System (IRIS). My curricula vita, including a list of my publications for the last ten years, is provided in Appendix A. A list of recent depositions and trial testimony is provided in Appendix B. My compensation is provided in Appendix C.

4. I am submitting this report at the request of WR Grace to address issues associated with vermiculite attic insulation. If new information becomes available that is relevant to the issues discussed in this report, I reserve the right to supplement the report.

EXECUTIVE SUMMARY

I have reviewed the available scientific data and studies related to asbestos exposures and risks associated with vermiculite attic insulation (VAI), and I have reviewed the relevant documentation and data provided by the claimants. I have also conducted a risk assessment to estimate the potential risks associated with VAI for residents and contractors. From this review and analysis, I have reached the following conclusions.

Conclusion 1: Health risk assessment is the scientifically appropriate and accepted methodology for assessing the potential cancer risk associated with VAI.

Risk assessment is the scientifically accepted process for assessing whether exposure to an environmental substance has a significant potential to cause adverse health effects. Risk assessment is routinely applied by Federal, state and local U.S. governmental organizations and international organizations, and is well accepted in the scientific community. In the risk assessment process, the estimated exposure of an individual takes into account the concentration, frequency and duration of exposures to a particular substance. The resulting exposure assessment for carcinogens includes a time-weighted average for a lifetime exposure and is compared with health effects data relating to the potential effects associated with a given exposure. From this comparison, the risk of individuals for adverse health effects is estimated.

Conclusion 2: I have evaluated the available exposure data from VAI disturbance activities and conducted a risk assessment according to accepted methodology with the useful data. The risks for residents are very low, and not of significant concern. The risks for contractors are higher than for residents, but are still below risk levels routinely accepted in the regulatory community or experienced in daily activities, and not of significant concern.

Seven modern studies were identified that provide personal exposure measurements for individuals engaging in activities that could lead to potential VAI exposure. Of these studies, three were found to be useful for risk assessment, and one other was found to be useful, but with caution. There are not specific studies available to estimate the amount of time residents and contractors may come into contact with VAI. Therefore, conservative assumptions were made about typical and high-end exposure durations for a variety of activities that may involve disturbance of VAI. These exposure frequency and duration estimates were combined with the personal exposure data to estimate typical and high-end lifetime average exposures to asbestos. The exposure estimates were compared

with a cancer potency value developed by the U.S. Environmental Protection Agency (EPA) to estimate the lifetime risk of cancer associated with VAI exposures. In general, the risk assessment employed conservative assumptions (i.e., assumptions that would tend towards overestimating risk), which must be accounted for in interpreting the results.

The estimated risks for residents were very low, and not a significant concern compared to the range of risks considered acceptable by the EPA and were lower than many other environmental risks and other common risks routinely accepted by people in their everyday lives. For contractors, the risks were higher than residents because the assumed exposure frequency and durations were higher. However, when making reasonable assumptions, the estimated risks were within ranges considered acceptable by EPA and below risk levels that are routinely accepted by the Occupational Safety and Health Administration (OSHA) for worker protection, and lower than many other occupational risks.

Conclusion 3: The EPA, with its contractor Versar, has also conducted a risk assessment for residents that engage in activities that disturb VAI, and found that the risks were within ranges considered acceptable.

In addition to the risk assessment presented in this report, the EPA recently conducted its own assessment for residents exposed to VAI. The study was conducted by Versar, an EPA contractor, and I have reviewed a draft of the study. This assessment showed that the risks to residences are low. There were some flaws with the risk estimates in that study that are discussed in this report, and the fiber counts were likely overestimated because cleavage fragments may have been counted and indirect preparation techniques may been used, both factors that artificially increase the risk estimates. These factors suggest that, despite the low risk estimates, the risks found in the EPA study are overestimates. This study may be regarded as a useful screening study (i.e., with a conservative, health protective approach, low risks were found). These findings are consistent with the results of my assessment.

Conclusion 4: The Agency for Toxic Substances and Disease Registry (ATSDR) recently conducted a medical monitoring study of residents of Libby, Montana. This epidemiologic investigation found that there was not an association between potential health impacts with residents having VAI in their homes or engaging in activities that disturbed the VAI.

In this medical monitoring study, ATSDR conducted chest radiographs and spirometry testing on a subpopulation of Libby residents that included 6,149 current or former

residents of Libby and the surrounding area. The study also included a questionnaire about potential exposure pathways for each resident. ATSDR conducted a correlation analysis of the medical and questionnaire to determine which exposure pathways were associated with evidence of asbestos exposure in the lung or decrements in lung function. Neither having VAI in a home nor handling VAI was associated with any effects. This provides more evidence that the risks to residents associated with VAI are not significant.

Conclusion 5: The findings from my risk assessment, the EPA/Versar risk assessment, and the ATSDR medical monitoring study are all consistent. The risks associated with VAI exposures are low, and are of a magnitude that is lower or similar to risks that are routinely experienced by individuals for environmental causes and other common activities, and accepted by regulatory agencies in setting standards.

The findings of my risk assessment, the EPA/Versar risk assessment, and the ATSDR medical monitoring study all show that the risks to residents associated with VAI are not significant. The consistency between these three studies provides a strong weight-of-the-evidence in support of this conclusion.

Additionally, the low risks that were estimated for residents and contractors are similar to or less than risks that are commonly experienced and accepted by individuals and regulatory agencies, both as the results of environmental causes or other common activities. In addition, the resulting risks are within the acceptable target range of risk, 10^{-4} to 10^{-6}, commonly accepted by EPA and far below risk levels associated with OSHA standards for worker protection.

Conclusion 6: The claimants have not conducted a risk assessment. Therefore, the claimants have not provided a scientific basis for showing that there are risks associated with VAI.

The claimants have not assessed the risk associated with VAI. For the most part, the claimants have presented some personal exposure data, without providing any context for how the data should be interpreted. There is a common saying in the medical literature: "the dose makes the poison," which dates back to the Enlightenment. This reference essentially means that the potential for disease from any type of exposure is a function of the frequency, duration, and magnitude of the exposure. In one case, the claimants compared some old measurement data to an OSHA standard that applies to workers. However, this OSHA standard is intended to protect workers routinely exposed to asbestos, as opposed to the infrequent exposures associated with VAI, and it is inappropriate to imply anything about risk from this comparison as time-weighted

averages for lifetime exposure (total dose averaged over a lifetime) have not been considered. Otherwise, the claimants have not attempted to show that the exposures that they measured may result in any adverse effects. Therefore, the claimants have not provided any scientific evaluation to show that exposures to VAI are harmful.

I. Vermiculite was commonly used as attic insulation. Some vermiculite attic insulation (VAI) that was sold by Grace contained small amounts of asbestos, and there is a potential for exposure to this asbestos. This report presents an assessment of the potential human health risks associated with VAI.

Vermiculite is a naturally occurring mineral that has been used in construction, insulation, and gardening products. When expanded, it has a shiny appearance and looks like small pieces of popcorn. Its light weight and structure make it a good insulation product, but also make it possible for some vermiculite to become airborne during a disturbance. Until 1984, Grace sold expanded vermiculite as attic insulation under the product name Zonolite.

The vermiculite used in Zonolite came from a mine in Libby, Montana. The ore from this mine contained a natural deposit of amphibole[1] minerals. Prior to being included in VAI, vermiculite was subjected to various production processes designed to remove naturally occurring impurities, including tremolite (2/5/03 Wood Dep. at 14-15). These processes involved, among other things, extensive use of screening and floatation devices at the Libby mine and mill as well as further screening at expansion plants and removal of fibers, including tremolite, during the expansion process itself. (2/26/03 Wolter Dep. at 28-30; 2/03 Yang Dep. at 26-28). Small amounts of asbestos may still be present in VAI that originated from the Libby mine. When left undisturbed, there is little, if any, chance for asbestos exposure. However, when disturbed through various activities in the attic, there is a potential for exposure to airborne asbestos fibers, but the levels of exposure are likely to be very low.

Asbestos is found in a variety of other materials that have been used in buildings, such as fireproofing materials, pipe insulation, air supply duct wrap, boiler insulation, and others (CPSC, 1979). Some of these materials contain up to 90% asbestos, and have been the historical motivation for the concern about asbestos exposures in buildings. Nonetheless, EPA generally recommends that these products not be removed from buildings, as long as the products are stable, because removal could ultimately lead to higher exposures (EPA, 1990). On the other hand, VAI generally contains less than 1% asbestos. By EPA regulations, products with less than 1% asbestos are not considered asbestos products for regulatory purposes (EPA, 1984; EPA, 1990a).

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[1] Amphibole refers to a particular type of mineral that contains asbestos.

This report addresses the risks associated with the VAI exposure pathway by applying commonly accepted methods for estimating and characterizing health risks. Risks to homeowners with VAI in their residences and risks to contractors that perform tasks in homes with VAI are considered.

II. Risk assessment is the accepted scientific method for evaluating the plausibility of an environmental exposure causing a disease, and can be specifically applied to estimate the potential for health impacts during disturbances of VAI. Risk assessment is a scientific, rigorous methodology that is widely accepted in the scientific community and by state, Federal, and international organizations. However, the claimants' experts have not conducted risk assessment. Therefore, the claimants have not provided an analysis that meets minimum scientific standards for demonstrating that exposures associated with VAI are harmful.

A. Risk assessment is the scientifically appropriate method for assessing the likelihood that environmental exposures are associated with disease, and can be applied to investigate the plausibility that disturbance of VAI will lead to adverse health effects.

A health risk assessment can establish if an exposure is at least plausibly linked to adverse health effects. In a risk assessment, the estimated exposures are compared to health benchmarks to determine the likelihood that the exposure could result in an adverse health effect. Risk assessment is a scientifically accepted methodology that is widely used by U.S. Federal, state, and local agencies, and international organizations to address issues of potential health effects.

The claimants' experts in this case have not conducted a health risk assessment to determine the plausibility of health effects associated with VAI exposure. Therefore, they have failed to provide any scientific basis for showing the plausibility of adverse health effects associated with VAI exposure.

B. The National Research Council of the National Academy of Sciences established a paradigm for conducting risk assessments, which is widely accepted by the scientific community and applied by governmental organizations in the U.S. and internationally.

In 1983, the National Research Council (NRC) published a document entitled *Risk Assessment in the Federal Government: Managing the Process* (NRC, 1983).

At the time, I was the Director of the Office of Health and Environment Assessment at the EPA, and I served as an advisor to the committee and a reviewer for this document. The document established health risk assessment as the acceptable approach for assessing risk associated with exposure to environmental substances. It is now considered an essential text for health risk assessment. The document outlined a four-step process for risk assessment:

1) *Hazard identification*: the identification of a compound as a potential hazard based on animal toxicity studies or human epidemiologic studies.
2) *Dose-response assessment*: the assessment of the dose required to cause particular health effects.
3) *Exposure assessment*: an estimation of the exposure of the compound from the particular activity in question.
4) *Risk characterization*: characterization of the evidence that an agent might be a human carcinogen (or cause other noncancer effects) together with a comparison of the exposure and dose-response to estimate the potential risk, accounting for uncertainties.

This four-step process is now often referred to as the "risk paradigm," and is widely accepted and applied by governmental authorities throughout the world and by the scientific community.

C. *The claimants in this case did not conduct a risk assessment, and have not provided any rigorous analysis that demonstrates the plausibility that exposures from VAI disturbances will lead to adverse health impacts. The only attempt by the claimants to associate VAI exposure with such adverse health effects was to compare airborne measurement data with the Permissible Exposure Limit (PEL) from the Occupational Health and Safety Administration (OSHA) and make inappropriate implications from this comparison.*

Claimants' expert Mr. Ewing compared exposure measurements during VAI installation simulations conducted by WR Grace in the 1970s to the OSHA PEL at the time (see Ewing expert report, pages 15-17) and drew inappropriate conclusions from this comparison. Further, Mr. Ewing notes that the current OSHA PEL is lower (i.e., more restrictive).

However, as Mr. Ewing states, the OSHA standards do not apply to homeowners. The PEL is set to protect workers, and is currently set at 0.1 fiber/cc over an 8-hour average period (i.e., a workday). As a regulatory standard, the PEL is based

on a concentration averaged over a workday. However, the cancer risk associated with asbestos exposure is not determined by looking at the exposure in a single day. Instead, the risk is determined as a function of the frequency, magnitude, and duration of exposure over a lifetime. OSHA recognized this in setting the current PEL. In developing the PEL, OSHA developed a dose-response model to assess the risk (or the individual probability of mortality from cancer) as a function of asbestos exposure. In its 1984 rulemaking, OSHA presented risks for workers exposed for 1, 20, and 45 years of full-time employment in a workplace with potential asbestos exposure (U.S. Department of Labor, 1994). Thus, the PEL is designed to reduce the risks of workers that are continuously exposed to asbestos over a long period of time. For infrequent exposures, it is inappropriate to imply that exceeding the PEL will result in any adverse health effects. The use of a dose-response model that is based on lifetime exposure is the most scientifically accurate way to assess the risks associated with infrequent exposures.

The exposure durations considered by OSHA for workers in a job that will result in routine exposure to asbestos are appropriate. However, it is unlikely for residents with VAI in their homes to be routinely exposed to asbestos at a frequency and duration of a person in a workplace with asbestos. Instead, most homeowners are likely to be exposed just a few times a year when they go into their attic and perform tasks, such as moving boxes that may result in a disturbance of the VAI. For homeowners involved in renovation activities, these tasks may be performed more frequently than for the typical homeowner, but the frequency and duration of exposure would still not present a significant risk. Additionally, for some of the tasks that may result in the highest exposures such as clearing or removing the VAI, the homeowner exposure frequencies are even lower. With respect to the removal of VAI, it is likely that a resident would only remove VAI, if at all, once or twice in their lifetime.

For a contractor that performs work in homes that have VAI, the exposure frequencies will likely be higher than most residents. However, most homes do not have VAI. The EPA estimates that about 1 million homes in the United States contain VAI (Versar, 1982). As Zonolite was not sold after 1984, this EPA estimate is likely a reasonable value for homes with VAI that contain any Libby amphiboles. Furthermore, most contracting activities do not take the contractor into the attic to perform a task that may result in disturbances of VAI. There are a series of events that must happen for a contractor to be exposed to VAI:

1) The contractor must go to a job at an older home, as homes built after 1984 would not have VAI.
2) The older home must have VAI. There are several other types of insulation that have been or currently are used. Only about 1% of homes in the U.S. have VAI.
3) The contractor must engage in an activity that disturbs the VAI. Many contracting activities do not take place anywhere near the attic, such as renovations in the living area or work on the exterior of the home. To disturb the VAI, the contractor must either engage in an activity in the attic (and spend a significant amount of time there for any significant exposure) or engage in some other activity that disturbs the insulation, such as drilling a hole in the ceiling below the attic.

All of these events must occur together for there to be an exposure to VAI.

III. The risk assessment paradigm is the only accepted methodology that can be used to address risk associated with exposure to VAI.

A. Hazard Identification: *The weight-of-evidence that asbestos causes cancer in humans is based on a series of epidemiologic studies in which workers have been exposed to asbestos at high concentrations, with frequent exposures over a considerable period of time or for individuals that were similarly exposed. The observed health effects associated with asbestos exposure include lung cancer and mesothelioma, and noncancer effects such as asbestosis.*

It is widely known and accepted that repeated exposures to high levels of asbestos over a long period of time may result in lung cancer and mesothelioma, which is a cancer of the pleural lining of the lung. The EPA classifies asbestos as a Class A carcinogen, or a known human carcinogen based on epidemiologic data gathered from exposures in the workplace[2]. Additionally, repeated exposure to high levels of asbestos is associated with asbestosis, a chronic inflammation of the lung.

The health effects associated with asbestos exposure are known as the result of numerous epidemiologic studies on workers in the asbestos industry, who were exposed to very high levels of asbestos over long periods of time. Additionally, some of these epidemiologic studies were done on miners or other workers exposed specifically to Libby amphiboles (McDonald et al., 1986; Amandus et

[2] http://www.epa.gov/iris/subst/0371.htm

al., 1987), providing evidence that Libby amphiboles are a health risk at high exposures that are sustained over a long period of time.

B. *__Dose-response assessment__: The EPA has published a review of asbestos health effect studies and has developed a recommended potency value for estimating the theoretical risk associated with a given asbestos exposure. Use of the EPA cancer potency value provides a conservative, upper-bound estimate of the risk.*

Simply stating that asbestos is associated with adverse health impacts is not sufficient to conclude that there will be adverse health effects associated with exposure from disturbing VAI. The manifestation of adverse health impacts depends upon the frequency, duration, and magnitude of exposure, or sometimes commonly said as "the dose makes the poison." The asbestos exposure associated with VAI is substantially lower than the exposures of the asbestos workers that were found to have elevated levels of disease. Therefore, it is necessary to estimate the likelihood of adverse health effects as a function of the actual exposure to asbestos from VAI.

EPA evaluates the available health effects data for environmental contaminants, and develops potency values that can be used for risk assessment. These reviews are cataloged into EPA's Integrated Risk Information System (IRIS). IRIS is widely used by EPA for internal risk assessments used in the regulatory decision-making process. IRIS is also frequently used by other governmental agencies and by members of the scientific community.

EPA has an IRIS file for asbestos which reviews the available human epidemiologic and animal toxicology data and recommends a cancer risk value of 0.23 per fiber/ml, based on the human epidemiologic data and using an exposure metric called PCM-equivalent (discussed in the exposure assessment section that follows). The value represents a probability of developing cancer for a lifetime average exposure of 1 fiber/ml. It is important to note that the risk factor is conservative and only to be compared with the __average__ exposure over a lifetime. Therefore, periods where there is no exposure to asbestos must be accounted for when developing this average value. The occurrence of cancer from environmental exposures is generally the result of prolonged, elevated exposures. Thus, the total exposure over a lifetime must be taken into account.

The EPA cancer risk potency represents a theoretical risk that is likely higher than the actual risk, particularly for the low exposures associated with VAI. For

example, in the EPA model, the cancer risk is assumed to be linear with exposure; thus, for example, if the exposure is decreased by 6-fold, the risk is also assumed to decrease 6-fold. This approach was adopted by the EPA in 1976 to place a plausible upper-bound on the risk, meaning that the real risk could be considerably lower, even approaching zero. In fact, at doses lower than those in the epidemiologic studies used to estimate the IRIS potency factor, the risk is unknown and could be considerably lower even approaching zero. The linear assumption is conservative, and is made to be precautionary and public health protective as prescribed by environmental statutes. As an example, for a person with a lifetime average exposure to asbestos of $4.3x10^{-6}$ fibers/ml, the theoretical cancer risk would be 1 in a million as follows:

$$4.3x10^{-6}\,\frac{fibers}{ml}[exposure]*0.23\frac{ml}{fiber}[risk\ factor]=10^{-6}[risk\ estimate]$$

However, it is possible that the risk is lower or approaching zero at this low level of exposure. Currently, there is no other available methodology for assessing the risks of low-level asbestos exposures. However, if a method is developed, I may reserve the right to update this analysis.

The level of exposure that causes asbestosis is generally considered higher than the level that causes cancer. Therefore, a risk assessment based on cancer potency should also be protective for asbestosis (Berman and Crump, 2001).

The same methods that were used to develop the EPA cancer potency value in IRIS were applied to the epidemiologic studies specific to the Libby amphiboles in VAI (Moolgavkar, 2002). The estimated potency values were similar or lower than the IRIS value, which suggests that Libby amphiboles are of similar or lower potency than the types of asbestos used to develop the EPA potency factor.

C. *Exposure assessment: There are several studies that have been conducted that have measured exposures during disturbance of VAI. However, the nature of the sample collection and asbestos measurement methodology is important for assessing the appropriateness of any measurement data for use in a scientifically reliable risk assessment.*

The available measurement studies of exposure during VAI disturbances are reviewed in the next section. This section provides some of the criteria for the use of asbestos exposure data in a scientifically reliable risk assessment.

1. <u>The appropriate measurement of exposure is the concentration of airborne fibers. Little information about risk can be obtained from dust measurements or measurements of the asbestos content of VAI.</u>

   The EPA cancer risk factor is based on the inhalation exposure to airborne asbestos or asbestiform fibers, as is the OSHA PEL. Therefore, airborne asbestos fiber exposure is the appropriate measure for exposure assessment. Sometimes dust measurements, including a percentage or quantification of the dust that is asbestos, are reported. Dust measurements may be useful for determining the presence of asbestos, but are not relevant for quantitative risk assessment. Additionally, measurements of the asbestos content of VAI may also be made. These measurements are useful for determining the presence of asbestos, but are not useful for estimating risks. Also, the presence of certain minerals (e.g., tremolite) in VAI does not necessarily mean that asbestos is available to become airborne. The VAI must be disturbed before any asbestos becomes airborne. Even during disturbance of VAI, not all asbestos will become airborne. Only those particles of respirable size dimensions are relevant to a proper risk assessment.

2. <u>For a proper comparison with the EPA cancer risk factor, exposure measurements must be collected using Transmission Electron Microscopy (TEM) and converted to an equivalent value for Phase Contrast Microscopy (PCM), or a PCM-equivalent (PCME).</u>

   There are two microscopic techniques that are commonly used for measuring asbestos fibers that are collected in air. TEM is the most sensitive measurement technology; it can detect the widest size range of fibers and can differentiate between asbestos and non-asbestos fibers. The older and less sensitive technique is PCM. The PCM method cannot distinguish between asbestos and non-asbestos fibers, and cannot detect as small a size of fibers compared to TEM.

   Historically, most exposure measurements from the epidemiologic studies that formed the basis of the EPA cancer risk factor were done using PCM. Therefore, the EPA risk factor is based on asbestos fiber counts using PCM, which may be smaller than TEM counts as a result of the lower sensitivity. For this reason, fiber counts from TEM measurements cannot be compared with the EPA risk factor without an adjustment. On the other hand, the PCM

measurements in the epidemiologic studies were made in environments with large amounts of asbestos; thus, the inability to differentiate asbestos and non-asbestos fibers did not significantly affect these fiber counts. By contrast, PCM measurements in non-occupational environments, such as a home, where other types of structures other than asbestos are present (e.g., in the airborne dust during a disturbance of vermiculite) may result in overestimates of fiber counts. Therefore, the appropriate exposure measure is with fiber counts from TEM, and converted to a PCME (or PCM-equivalent) by excluding fibers in the size range that could not be measured by PCM and with appropriate determination of which fibers are asbestos. Specifically, only TEM fibers greater than 0.4 microns (µm) in diameter and greater than 5 µm in length should be included in the PCME fiber counts.

This concept is outlined in EPA's IRIS file on asbestos, which states: "The unit risk is based on fiber counts made by phase contrast microscopy (PCM) and should not be applied <u>directly</u> to measurements made by other analytical techniques" (emphasis ours). Further, the IRIS file states: "It should be understood that while TEM can be specific for asbestos, PCM is a nonspecific technique and will measure any fibrous material. Measurements by PCM which are made in conditions where other types of fibers may be present may not be reliable." These statements have been interpreted to develop the PCME concept, and the EPA has routinely applied it in risk assessments.

3. <u>The asbestos concentration can be overestimated if the indirect filter preparation technique is used. The direct preparation technique should be used for the most accurate results.</u>

Sometimes filters collected in dusty environments can be overloaded if an improper sampling volume is collected. In these situations, some microscopists manipulate the filter, such as through sonication, to produce a suspension of particles in a transfer medium, which is then filtered onto a new filter for analysis. According to the expert report of Dr. Richard Lee, the indirect preparation of the filter can breakup asbestos bundles and clusters that were single structures in the air into numerous individual fibers (Lee, 2003). This manipulation results in an overestimate of the actual asbestos concentration in the air. In addition to their own analysis, Dr. Lee cites an EPA report which also found that the indirect transfer technique leads to higher fiber counts than the direct transfer technique (EPA, 1990b).

4. Many samples taken in an environment with asbestos may contain cleavage fragments. Cleavage fragments are not asbestiform material and are, at the least, not as toxic or carcinogenic as asbestiform fibers. Therefore, cleavage fragments must be considered separately in fiber counts for appropriate risk assessment.

While certain amounts and sizes of asbestiform fibers are known to be carcinogenic, the same is not true of tremolite cleavage fragments, which also may appear in microscopic analyses of amphibole asbestos. As Dr. Ilgren has certified in his expert report, there are fundamental differences in the properties of cleavage fragments and asbestiform fibers that explain the observed differences in carcinogenic potential (Ilgren, 2003). Asbestos fibers generally exist as bundles of very long, thin fibers that display extreme strength, flexibility, durability, and acid resistance. Cleavage fragments do not have these properties. Cleavage fragments are formed when nonasbestiform amphibole is crushed and slivers of mineral randomly break off (or "cleave") from the parent material so that they may look like fibers. However, cleavage fragmentation does not yield significant quantities of long, thin fibers of the dimensions that contribute substantially to carcinogenic risk. Instead, cleavage fragments are brittle and weak, and lack strength, durability, and acid resistance. In stark contrast to asbestos fibers, cleavage fragments are not strongly biopersistent in the human body, which significantly limits the toxicological potential.

Dr. Ilgren provides a review of the available animal toxicology and human epidemiologic data on cleavage fragments, and concludes that cleavage fragments are not carcinogenic. To the best of my knowledge, the claimants make no mention whatsoever of cleavage fragments in their reports and have failed to separate cleavage fragments from asbestiform fibers in their fiber counts. The lack of any consideration of cleavage fragments by the claimants represents a serious scientific deficiency in their reports.

It is important to note that EPA has advised that cleavage fragments should not be included in fiber counts for comparison with its IRIS cancer risk factor (Lioy et al., 2002).

D. *Risk characterization: EPA and other regulatory authorities have established criteria for assessing the acceptability of risks, which can be applied to characterize the magnitude of the risk associated with VAI.*

After developing quantitative estimates of risk, or the probability of an individual getting a disease from an exposure, it is necessary to establish what risk is acceptable. It must be understood that we accept small risks in our everyday lives, from driving to work, to what we eat, or how we spend our recreational time. Regulatory authorities are concerned with risks that are considered unacceptable to citizens. The definition of an acceptable risk is a value judgment that takes into account many factors, including the uncertainty in the assessment, the costs of remedial action, and the magnitude of risks that are generally found to be acceptable to individuals. This report relies on ranges of acceptable risk established by the EPA, and used in EPA regulatory actions.

For carcinogens, EPA has set forth and supports an acceptable risk range of individual risk from cancer of 10^{-6} (one in a million) to 10^{-4} (one in ten thousand). For example, the National Contingency Plan (NCP) sets forth the procedures that must be followed by EPA and private parties in selecting and conducting Superfund response actions. The NCP defines the acceptable risk range as follows:

> "For known or suspected carcinogens, acceptable exposure levels are generally concentration levels that represent an excess upper bound lifetime cancer risk to an individual of between 10^{-4} and 10^{-6} using information on the relationship between dose and response."

EPA expanded on its definition of the acceptable risk range in 1991 in its document "The role of baseline risk assessment in Superfund remedy selection decisions" (EPA, 1991):

> "For sites where cumulative site risk to an individual based on reasonable maximum exposure for both current and future land use is less than 10^{-4}, action is generally not warranted, but may be warranted if a chemical specific standard that defines acceptable risk is violated or unless there are noncarcinogenic effects or an adverse environmental impact that warrants action."

The acceptable risk range has also been adopted by other programs within EPA, including the drinking water (Cotruvo and Vogt, 1990) and air (NRDC v. EPA, 1987) programs.

In the decision established through the NRDC v. EPA case, often referred to as the Benzene Decision, EPA adopted a presumptively safe risk level of 10^{-4}. Furthermore, in setting this risk level, EPA noted that as risk increases incrementally above the benchmark of 10^{-4}, it becomes "presumptively less acceptable." In establishing this level, EPA stated that the 10^{-4} risk level is not a "rigid line for acceptability," but that the "Agency intends to weight it with a series of other health measures and factors" when making a decision (54 Federal Register 38044).

IV. There are several studies that have measured asbestos exposures during disturbances of VAI. Those studies are of varying quality and utility for risk assessment.

A. We have identified seven modern studies that have measured asbestos exposures during disturbances of VAI.

The following studies were identified that have measured exposures to asbestos during VAI disturbance:

- *Barbanti:* This study was conducted by plaintiffs as part of the *Marco Barbanti vs. WR Grace & Company et al.* litigation (*Barbanti*). At a residence containing VAI in Washington State, exposures were measured during simulated remodeling and renovation activities.

- *Lees and Mlynarek*: This study was sponsored by WR Grace and the principal investigators were industrial hygiene professors at The Johns Hopkins School of Public Health and the University of South Florida. Exposure measurements were made in a VAI-containing home during simulated homeowner maintenance and renovation activities (Lees and Mlynarek, 2003).

- *Libby, Montana/EPA*: This study was conducted by the U.S. Environmental Protection Agency in Region 8, as part of its evaluation of risks to residences in Libby, Montana. Exposure measurements were made in several homes both without any disturbance activities and during disturbance activities. In addition to the exposure measurements, EPA developed risk estimates associated with potential VAI disturbances in Libby (Weis, 2001). After correction of numerous flaws in EPA's

database and the addition of measurements not included in the EPA report, there are a total of 44 TEM personal air samples with direct preparation. Only 4 of the 44 measurements (9.1%) have asbestiform fibers, and only 17 measurements (38.6%) have either asbestiform fibers or cleavage fragments. Any estimates of risk from VAI exposures in Libby must account for these additional measurements.

In addition to the measurement data, the Agency for Toxic Substances and Disease Registry (ATSDR) conducted a medical monitoring study in Libby. ATSDR conducted chest radiographs and spirometry testing (i.e., a measurement of lung function) on a subpopulation of 6,149 current or former residents of Libby and the surrounding area. A questionnaire was administered to gather information on the potential pathways of exposure for each study subject. A statistical analysis of the questionnaire and the medical monitoring data failed to find any association between lung abnormalities and either having vermiculite in the home or handling vermiculite insulation. The ATSDR study shows that VAI exposures anticipated to be far lower than levels found to be associated with cancer and asbestosis in epidemiologic studies were not associated with lung abnormalities. This result provides significant evidence that exposures associated with VAI do not cause a cancer risk. This study is also discussed in the risk characterization section of this report.

- *Claimants, Silver Spring:* The claimants in this case made exposure measurements during cleaning activities in a home with VAI in Silver Spring, Maryland (Hatfield et al., 2003).

- *Claimants, Washington State:* The claimants in this case made exposure measurements during disturbances of VAI in several homes in the state of Washington (Ewing et al., 2003).

- *Pinchin Environmental:* This study measured exposures during the demolition of a building containing VAI in Canada (Pinchin Environmental, 1992).

- *Versar/EPA:* The study was conducted by the consulting firm Versar, and sponsored by the U.S. EPA. During several activities to disturb VAI, exposure measurements were made in five homes in Vermont and in an experimental chamber (Versar, 2002). I was a peer reviewer of this

document, and submitted comments to EPA (Anderson, 2002). Versar also conducted a risk assessment with this data, and found that the risks were generally minimal. The results of the Versar/EPA risk assessment will be discussed in more detail in the next section.

The next section provides an evaluation of each of these studies for quality and utility for risk assessment.

B. *The criteria described in Section III were used to evaluate each of the exposure studies for scientific quality and appropriateness of use in assessing risks.*

There are several criteria that were applied to assess the scientific quality of the studies and their usefulness for risk assessment:

1) *Appropriate exposure scenarios and adequate descriptions*: The study must have exposure scenarios that are appropriate and typical for residential and/or contractor renovation activities in an attic. These exposure scenarios must be described in sufficient detail to clearly understand the activity.

2) *PCME fiber counts*: PCME data is the exposure metric that must be available to make appropriate comparisons with the EPA IRIS potency factor. Without PCME data, it is not possible to conduct a scientifically defensible risk assessment.

3) *Use of direct sample preparation*: The use of indirect preparation of samples has the potential to cause overestimates in fiber counts. Therefore, studies that use indirect preparation are not appropriate for risk assessment.

4) *Separation of cleavage fragments*: Dr. Ilgren has certified that cleavage fragments are not carcinogenic (Ilgren, 2003). Therefore, it is appropriate to separate cleavage fragments from asbestiform fibers in summarizing the fiber counts. Further, EPA has advised that cleavage fragments should not be included when assessing risk using the EPA IRIS potency factor (Lioy et al., 2002).

5) *Other issues*: Other issues relevant to using the data for risk assessment, such as sample collection, measurement issues other than those mentioned above, and whether the study contains sufficient documentation.

C. *The studies are of varying quality when evaluated with the criteria for use in risk assessment.*

For each of the seven studies, Table IV-1 reviews the results of the analysis of the first three criteria. Table IV-2 reviews the fourth and fifth criteria and provides an overall summary of the review for each study.

The Versar/EPA study represents the most extensive measurement data of potential VAI exposures. Data were collected in five homes, and an experimental chamber was built for the study. The Versar/EPA risk assessment generally found that there were no significant risks associated with any of the scenarios. However, in the next section, risk estimates are provided based on refined exposure duration assumptions. While the Versar/EPA study was well conducted with respect to developing plausible exposure scenarios for VAI disturbances, there are some issues associated with the measurement data. The potential problems with the measurements include the lack of PCME fiber counts, the apparent use of indirect preparation, and the lack of any discussion of cleavage fragments. However, all of these issues will result in overestimates of fiber counts. Therefore, the Versar/EPA study provides a useful bounding estimate[3] of the risk associated with VAI, and can be useful as a screening study[4].

The Lees and Mlynarek study contains the most accurate fiber count data. This study provided PCME concentrations, used direct preparation of samples, included a count of the cleavage fragments, and provided detailed descriptions of disturbance scenarios that are appropriate. The report is of a scientific quality that would warrant consideration for publication in a peer-reviewed journal. Although this study was not as extensive as the EPA/Versar study with respect to the number of testing locations, the fiber counts from the scenarios that were included were collected in the correct manner for accurate risk assessment.

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[3] A bounding estimate is an estimate that places a limit on the risk, but the actual risk is likely lower.
[4] Screening-level estimates are typically used for screening out those risks which may require further study from risks that are low even using high-end conservative data and assumptions, where no further study is necessary.

In addition, the claimants' data collected in the state of Washington mostly provide the necessary components for risk assessment, following a reanalysis of the fiber counts by Dr. Richard Lee (Lee, 2003). The claimants did not separate the cleavage fragments from the asbestiform fibers, and did not include PCME fiber counts. However, from an analysis of the fiber count sheets provided by the claimants, Dr. Lee was able to separate the cleavage fragments from the asbestiform fibers. Therefore, the claimants' data from the state of Washington can be used for risk assessment with the caveat that there is some uncertainty in the fiber counts.

The Libby/EPA data are extensive, including 44 separate personal exposure measurements during VAI disturbances (including only direct preparation samples). Dr. Lee has provided a reanalysis of the EPA data with PCME fiber counts, with and without cleavage fragments. However, there are a number of other measurement problems associated with these data (Lee, 2002). Additionally, the investigators provided very little description of the disturbance activities, which limit the usefulness of these data for risk assessment. Given these issues, I have concluded that the Libby data can only be used for a bounding assessment (with Dr Lee's reanalyzed fiber counts) with appropriate caution because of the uncertainties in what activities were performed.

There were several studies which do not provide any data that can be used for a scientifically reliable risk assessment. The Pinchin Environmental study includes data that were collected during a building demolition. A demolition is not relevant to a risk assessment for residents, and is not a typical scenario for contractors. It is expected that workers would wear respiratory protection during a demolition, which would reduce exposure. In addition, there were several measurements problems with this study, including the use of indirect sample preparation.

The claimants' data from the Silver Spring study is not useful for risk assessment because there is no description of the measurement methods, and there is only a brief description of the study. For this study, the claimants also did not provide PCME concentrations or a separation of cleavage fragments. For the *Barbanti* data, there are also serious measurement problems according to Dr. Lee that make the data inappropriate for risk assessment, including the use of indirect preparation of sample filters.

Table IV-3 provides a characterization of the usefulness of each VAI exposure study in risk assessment. The next section of this report presents a risk assessment based on the best available data.

Table IV-3. Summary of the Usefulness of Each VAI Exposure Study for Risk Assessment

Useful for Risk Assessment	Useful for a Bounding Assessment with Caution	Not Useful for Risk Assessment
Lees and Mlynarek Claimants, Washington State[a] Versar (EPA)[b]	Libby, Montana	Pinchin Enviromental Claimants, Silver Spring *Barbanti*

[a] This study only meets the required criteria after the reanalysis of the fiber counts by Dr. Richard Lee, and there is still some uncertainty in the reanalyzed fiber counts, since Dr. Lee did not do the original microscopic analysis.

[b] Because of issues associated with the measurements, the fiber counts are considered bounding estimates, and the study is useful as a screening study (i.e., despite factors that would overestimate risk, low risks were found).

Table IV-1. Review of Criteria 1 through 3 for the VAI Disturbance Exposure Studies

Study	Appropriate Exposure Scenarios and Adequate Descriptions	PCME Fiber Counts	Use of Direct Preparation Method
Barbanti	Measurements were made during residential maintenance and remodeling scenarios. A description and videotape of the activities were provided.	Both PCM and TEM measurements were made, but PCME results were not reported.	Both direct and indirect preparation methods were used.
Pinchin Environmental	Exposure measurements were made during the demolition of a building, which is far more disturbance than for typical residential or contractor activities. This activity would typically be accompanied by respiratory protection. The study report adequately describes the activities.	PCM and TEM measurements were collected. TEM results are reported as fibers > 5µm, but the diameter criterion was not used. Therefore, PCME results are not provided.	The report does not make clear which preparation method was used, but the count sheets suggest that an indirect preparation was used.
Lees and Mlynarek	Measurements were made during typical residential maintenance and remodeling scenarios. The activities are described in detail in a technical report.	Both PCM and TEM measurements were made, and PCME results were reported.	Only direct preparation methods were used.

Study	Appropriate Exposure Scenarios and Adequate Descriptions	PCME Fiber Counts	Use of Direct Preparation Method
Libby, Montana	For most samples, it is not clear what activities were performed. There is no study report summarizing the activities or data. The data are stored in a database that has numerous flaws, errors, and inconsistencies (Anderson, 2002). There are only very brief descriptions of activities, and only for some samples.	Both PCM and TEM measurements were made, and PCME results were developed by Dr. Lee from the count sheets. However, some risk calculations were done with PCM, which is inappropriate under EPA standards.	Both direct and indirect preparation methods were used. Cleavage fragments were included in the fiber counts, although, in some cases, the count sheets are available to estimate the prevalence of cleavage fragments.
Claimants, Silver Spring	Exposure measurements while clearing an attic area for storage. A sample log of the activities is provided, and some photographs are included.	There is no description of the methodology used to estimate the fiber counts. The only note is that the counts include fibers > 5µm, but the PCME definition also includes a diameter requirement. Therefore, PCME results are not provided.	There is no description of the measurements methods provided.

Study	Appropriate Exposure Scenarios and Adequate Descriptions	PCME Fiber Counts	Use of Direct Preparation Method
Claimants, Washington State	Measurements were made during residential maintenance and remodeling scenarios. A detailed description of the activities is provided.	PCM and TEM measurements were collected. TEM results are reported as fibers > 5μm, but the diameter criterion was not used. Therefore, PCME results are not provided. However, Dr. Lee was able to develop PCME estimates by reviewing the count sheets.	It appears that the direct method was used for the measurements.
Versar (EPA)	Measurements were made during a variety of typical residential maintenance and remodeling scenarios. The report provides detailed descriptions of all of the disturbance activities. This study represents the most extensive measurement effort for exposures associated with VAI. The study provides the most disturbance scenarios, and the most number of separate homes, including an experimental chamber.	PCM and TEM measurements were collected. TEM results are reported as fibers > 5μm, but the diameter criterion was not used. Therefore, PCME results are not provided.	It appears that indirect preparation methods may have been used for some samples (Chatfield, 2002).

Table IV-2. Review of Criteria 4 and 5 for the VAI Disturbance Exposure Studies and a Summary of the Review

Study	Separation of Cleavage Fragments	Other Issues	Summary Comments
Barbanti	There is no mention in the report of cleavage fragments, and it's unclear whether these fragments are included in the counts.	Dr. Lee testified that the claimants collected an insufficient air volume for their samples.	Because of numerous issues with the measurements, these data are not useful for risk assessment.
Pinchin Environmental	There is no mention in the report of cleavage fragments, and it's unclear whether these fragments are included in the counts.		These data were collected during a demolition, which is not a typical activity and would likely be accompanied by respiratory protection. Additionally, indirect sample preparation was used, PCME fiber counts were not collected, and there is no mention of cleavage fragments.
Lees and Mlynarek	The PCME data are reported for asbestiform fibers only, but the appendices include the data for cleavage fragments.		This study provides all of the necessary components for use in risk assessment.

Study	Separation of Cleavage Fragments	Other Issues	Summary Comments
Libby, Montana	There are reports that describe the measurement methods generally, and some of the count sheets are available, but there is not a central report describing the data. A database is available summarizing the results, but there are significant flaws and inaccuracies in the database (Anderson, 2002; Lee, 2002).	There are additional data in Libby that EPA failed to report in its Libby assessments. Also, a medical monitoring study by ATSDR found that the VAI was not associated with health effects. The ATSDR study may provide more reliable information about risks than the risk assessment.	Due to numerous problems with the measurement data, data summaries, and the scant descriptions of the disturbance activities, these data can only be used for a bounding assessment of risk and with caution given the uncertainties.
Claimants, Silver Spring	There is no mention in the report of cleavage fragments, and it's unclear whether these fragments are included in the counts.	There is only a page and half description of the entire study.	Because there is no description of the measurement methods, PCME data are not provided, no mention of cleavage fragments, no mention of sample preparation technique, the study is inadequate for risk assessment.
Claimants, Washington State	There is no mention in the report of cleavage fragments, but Dr. Lee was able to separate the cleavage fragments from the asbestiform fibers, albeit with some uncertainty that would not have occurred if Dr. Lee did the original microscopic analysis.		As provided in the study reports, the data are only useful for a bounding assessment because PCME data are not provided, and cleavage fragments are not considered. However, with Dr. Lee's reanalysis, these data can be used, albeit with some uncertainty.

Study	Separation of Cleavage Fragments	Other Issues	Summary Comments
Versar (EPA)	There is no mention in the report of cleavage fragments, and it's unclear whether these fragments are included in the counts.	Chatfield (2002) and van Orden (2002) found that there were several flaws in the measurement methods, which would tend to result in overestimates of fiber counts.	This study provides the most extensive VAI exposure measurements available. However, there are some issues associated with the measurements that cause the fiber counts to be overestimated. Therefore, this study is useful for bounding estimates of risk, and as a screening level assessment.

V. A risk assessment can be conducted with the useable personal exposure data identified in the last section. These risks can be put into context given the uncertainties in the assessment. Additionally, there is other information available to characterize these risks.

A. *To estimate exposures for residents and contractors, reasonable durations for activities with contact with VAI must be established.*

1. Introduction

As discussed throughout this report, the cancer risk associated with asbestos is dependent on lifetime exposure. The risk associated with a particular activity can be estimated as follows:

$$\textit{Cancer Risk} = \textit{Cancer Risk Factor} * \textit{Exposure} * \textit{TWF} \qquad \text{(V-1)}$$

where the *Cancer Risk Factor* is the EPA/IRIS value 0.23 per fiber/ml, the *Exposure* is the average exposure over the time period of the activity, and the time-weighting factor (TWF). The TWF represents the fraction of time over a lifetime that an individual engages in a particular activity. Under EPA guidance, a 70-year lifetime is typically assumed, which equals 25,550 days or 613,200 hours. Therefore, the TWF can be estimated as follows:

$$\textit{TWF} = \frac{\textit{Hours Engaged in Activity}}{613{,}200\ \textit{hours / lifetime}} \qquad \text{(V-2)}$$

There has not been a specific study on the hours that a resident or contractor might be engaged in activities that would result in a disturbance of VAI. Therefore, conservative exposure durations were developed based on available information. It is recognized that individual behavior or work patterns will differ. Therefore, to account for variation in exposure and to facilitate calculation of central tendency and upper bound risks, "typical" and "high-end" exposure factors have been derived for both residents and contractors. This section provides the basis for the derivation of the activity specific TWFs used in the risk assessment.

If additional data becomes available to better characterize exposure durations, I reserve the right to update this assessment.

2. Exposure Scenarios

TWFs were generated for five exposure scenarios selected to represent the range of activities undertaken during the various simulation studies.

Scenario 1: *Moving/storing/cleaning boxes in VAI attic space*

This scenario is assumed to apply only to residents, because some of the contractor simulations include moving boxes as a part of another activity. It is assumed that the exposure duration for this scenario is a 0.5 hour (typical) and 1 hour (high-end) per event.

Scenario 2: *Small area clearance / wiring / moving aside VAI*

This scenario involves activities including removal and clearance of a small area of VAI, as might be done to provide access and repair to electrical wires and junction boxes and for minor renovations. This activity typically also includes replacement of VAI after the work is done and is assumed to take between 0.5 and 1.5 hours.

Scenario 3: *Small area clearance and fan installation.*

This scenario is similar to Scenario 2, but includes drilling a hole from below prior to clearance of VAI from the ceiling space above and installation of a ceiling fan with associated electrical wiring. This activity is assumed to take between 3 and 5 hours.

Scenario 4: *Large area clearance and refill.*

In this scenario, a large area of VAI is disturbed or moved aside, for example, in preparation for installation of attic space equipment or a skylight. This activity is assumed to take between 1 and 2 hours.

Scenario 5: *Removal of VAI.*

This scenario includes the removal of VAI for replacement with another type of insulation. The activities include scooping, bagging and sweeping activities. This activity is assumed to take between 8 and 12 hours.

Table V-1 shows how the various activities, as described in the simulation studies, were grouped under the scenario designations. This table is not necessarily meant to imply similarities in the activities for which differences are reflected in the air concentration data; rather the grouping allows for use of set standardized TWFs for consistent evaluation of the data and consistency in the risk estimates. In other words, for this risk assessment, the activities in the same scenario group are assumed to take up the same amount of a person's time.

Table V-1. Summary of VAI Disturbance Scenarios Matched to Activities Simulated in the Exposure Studies

Scenario	Lees and Mlynarek (2003)	Versar (2002)	Claimants' Washington State Study
1	Moving boxes	Using the attic with vermiculite insulation as a storage space	Cleaning stored items
2	Small area clearance	Wiring or small renovation in an attic containing dry vermiculite	Shop Vac removal of VAI from top perimeter wall cavities
3	Small area clearance with ceiling fan installation		Ceiling penetration
4	Large area clearance		Moving aside VAI (Grace method[5]/ homeowner method)
5		Removing vermiculite attic insulation	

[5] The claimants refer to the "Grace method," but it is not clear why it is given that name. Nonetheless, we have used their characterization in this report so that it is clear to which scenario in the claimants' study we are referring to.

3. Duration of Exposure (years)

Residents

For activities that can be expected to occur regularly, i.e., on annual basis, the years of exposure are based on the average and upper bound home tenures derived from population mobility studies. The average tenure in a home, 9 years, is assumed for the typically exposed resident, and the 90th percentile value, 30 years, is used for a high-end exposed resident (EPA, 1997).

Contractors

Contractors' exposure durations are reflective of occupational tenure. The exposure duration for typical contractors has been assumed to be 11 years. This value is approximately the same as the median occupational tenure for electricians, a profession with high occupational tenure relative to other contractors (Carey, 1988). The high end value is 45 years based on the assumption that an individual commences work at 20 years old and works as a contractor until 65 years of age.

4. Time Weighting Factors

The following summarizes the TWFs and discusses the important assumptions that were made in deriving the TWFs. The combination of time spent in an activity, exposure frequency and exposure duration is best described by the number of hours spent in a scenario during an individual's lifetime.

Residents

The amount of time that is assumed to be spent by typical and high-end exposed residents that are engaged in VAI disturbing activities and the corresponding TWFs (expressed as a percentage of a lifetime) are shown in Table V-2. These estimates include the potential for a homeowner to engage in home renovation activities that may disturb VAI.

Table V-2. Summary of Estimated Exposure Durations and TWFs for Residents

Activity	Scenario	Time Spent in Activity (hrs/day)	Exposure Frequency (days/yr)	Exposure Duration (years)	Total Events	Total Hours	Time Weighting Factor (%)
1 / Moving boxes	Typical	0.5	2	9	18	9	0.0015%
	High-end	1	4	30	120	120	0.020%
2 / Small area clearance	Typical	0.5	1	2	2	1	0.00016%
	High-end	1.5	1	5	5	8	0.0012%
3 / Small area clearance & fan installation	Typical	3	1	1	1	3	0.00049%
	High-end	5	1	2	2	10	0.0016%
4 / Large area clearance	Typical	1	1	1	1	1	0.00016%
	High-end	2	1	2	2	4	0.00065%
5 / Removing VAI	Typical	8	1	1	1	8	0.0013%
	High-end	12	1	1	1	12	0.0020%

Contractors

In this assessment, contractors are assumed to undertake the same activities as residents and take the same amount of time to complete the activity, but the frequency of exposure is assumed to be higher. Unlike residents, who are assumed to live in VAI-containing homes, a contractor will work in numerous homes during their working life. Therefore, the frequency of working in a VAI home and the probability that the contractor will undertake an activity that brings them into contact with VAI within a VAI home are important considerations.

It has been estimated that there may be about 940,000 homes in the U.S. with VAI (Versar, 1982), of the approximately 81 million homes in the U.S. (USDOC 1996)[6]. These data imply a frequency of VAI homes in the U.S. of about 1.16%. However, the frequency may be higher in colder climates. Therefore, for the upper-bound exposure scenarios, a 3.0% frequency of VAI homes was assumed, or nearly triple that national average. Using this information and the standard assumption of 250 working days per year, a contractor can be expected to spend, on average, 2.9 days per year in a VAI home, and 7.5 days as the high-end.

There are not specific data to indicate how frequently a contractor's work may include the disturbance of VAI. However, there are many activities that contractors perform in and around homes that do not require entrance to or significant time in the attic. Therefore, if a contactor enters a home with VAI, a value of 10% was assumed for the probability that a contractor would engage in an activity that would disturb the VAI. These assumptions may be very conservative.

Therefore, the number of days per year that a contractor may enter a home with VAI and engage in an activity that results in a disturbance of the VAI is estimated as follows:

*VAI Contact (days/yr) = Work Days * Prob(VAI-home) * Prob(VAI-activity)* (V-3)

where:

Work Days = Total number of working days per year for a contractor

[6] The value represents census data from 1993 for the flowing home categories: "single family detached", "single family attached" and "2 to 4 units". It is conservatively assumed that a residential contractor does not work in buildings with larger numbers of units, which, in any event, are not likely to contain VAI.

Prob(VAI-home) = probability that a particular home will have VAI (1.16% for typical and 3.0% for high-end)
Prob(VAI-activity) = probability that a contractor will engage in an activity that might disturb the VAI (10%)

Applying equation V-3, the exposure frequencies for activities involving disturbance of VAI for the typical and high-end contractor are 0.29 days per year and 0.75 days per year, respectively. The details of this calculation are shown in Table V-3.

Table V-3. Summary of the Derivation of Exposure Durations for Contractors

Exposure Factor	Typical Scenario	High-End Scenario	Note
Homes with VAI	940,000	940,000	Versar (1982)
Total Homes	81,094,000	81,094,000	US DOC (1996)[a]
Frequency of VAI homes	1.16%	3.0%	calculated/assumed
Working days / year	250	250	assumed
Days working in VAI home / year	2.9	5.0	calculated[b]
Probability of Contact with VAI in VAI home	10%	10%	assumed
Days contacting VAI / year	0.29	0.75	calculated

[a] The value used represents the sum of homes in the following categories: "single family detached" (64,283,000 units), "single family attached" (6,079,000 units) and "2 to 4 units" (10,732,000 units).
[b] The VAI-home EF is the frequency of VAI homes multiplied by the number of working days per year.

The hours spent engaged in activities involving contact with VAI by typical and high-end exposed contractors and the corresponding TWFs (expressed as a percentage of a lifetime) are summarized in Table V-4.

Table V-2. Summary of Estimated Exposure Durations and TWFs for a Contractor

Activity	Scenario	Time Spent in Activity (hrs/day)	Exposure Frequency (days/yr)	Exposure Duration (years)	Total Events	Total Hours	Time Weighting Factor (%)
2 / Small area clearance	Typical	0.5	0.29	11	3	2	0.00026%
	High-end	1.5	0.75	45	34	51	0.0083%
3 / Small area clearance & fan installation	Typical	3	0.29	11	3	10	0.0016%
	High-end	5	0.75	45	34	169	0.028%
4 / Large area clearance	Typical	1	0.29	11	3	3	0.00052%
	High-end	2	0.75	45	34	68	0.011%
5 / Removing VAI	Typical	8	0.29	11	3	26	0.0042%
	High-end	12	0.75	45	34	405	0.066%

B. Using the exposure duration assumptions, lifetime average exposure estimates can be developed for residents and contractors with the personal exposure data that is useful for risk assessment. Cancer risks can be estimated for each exposure estimate using the recommended EPA dose-response model for asbestos.

The risk estimates are summarized in Tables V-5 through V-8. The tables contain the following:

- *Table V-5*: risks for residents for asbestiform fibers
- *Table V-6*: risks for contractors for asbestiform fibers
- *Table V-7*: risks for residents for asbestiform fibers plus cleavage fragments
- *Table V-8*: for contractors for asbestiform fibers plus cleavage fragments

Tables V-5 and V-6 include risk estimates for the Lees and Mlynarek and Claimants-Washington studies. Because the EPA/Versar study likely includes cleavage fragments, it was not included in the tables for asbestiform fibers only. Table V-7 and V-8 includes risks for Lees and Mlynarek, Claimants-Washington, and Versar/EPA. However, because cleavage fragments are not classified as carcinogenic and not counted under EPA/IRIS and OSHA, the risks in these tables are overestimates of the actual risk. Appendix D contains detailed tables showing all of the fiber concentrations from each study and scenario, the corresponding TWFs, and the estimated risks.

When appropriate data were available, risks were calculated for the workers engaged in the activities, any helper in the vicinity of the activity, and a bystander who may have been in the home but not in the attic during the disturbance. For each scenario and type of exposed individual, a typical and high-end exposure was estimated.

When there were no fibers detected for a particular sample, a value of zero was used (Oehlert et al., 1995), consistent with the procedures used by EPA/Versar and by EPA Region VIII in its assessments in Libby. For the typical residential scenarios, an average count was used to estimate risk when there were multiple samples. For the high-end residential scenario, the maximum fiber count was used to estimate risk. For contractors, the average fiber counts were used for the typical and high-end scenarios, reflecting that the contractor would likely be

exposed to average concentrations over time by conducting activities in various homes.

Risks were estimated for the separate activities in the studies (i.e., moving boxes, small area clearance, etc.). Additionally, the aggregate risk of all these activities (i.e., the combined risk) was also calculated. This estimate is conservative because it assumes that the resident engages in all of these activities on separate occasions. By calculating an aggregate risk, I have essentially increased the exposure frequencies derived in Table V-3.

Table V-5. Estimated Plausible Upper-Bound Risks for Residents for Asbestos and Asbestiform Fibers

Activity	Residents					
	Worker		Helper		Bystander	
	Typical	High End	Typical	High End	Typical	High End
Based on Lees and Mlynarek						
Moving Boxes	1.7E-09	1.4E-07	0	0	0	0
Small Area Clearance	3.7E-08	5.8E-07	2.7E-09	8.2E-08	0	0
Small Area Clearance & Fan Installation	0	0	0	0	0	0
Large Area Clearance	6.2E-09	6.2E-08	1.1E-09	5.6E-09	0	0
Aggregate Risk	**4.5E-08**	**7.8E-07**	**3.8E-09**	**8.7E-08**	**0**	**0**
Based on Claimants' Washington State Study						
Cleaning Stored Items	0	0	0	0	--	--
Ceiling Penetration	5.6E-08	1.9E-07	1.3E-07	4.3E-07	--	--
Moving Aside VAI - Grace Method	2.0E-07	7.8E-07	0	0	--	--
Moving Aside VAI - Homeowner Method	2.1E-07	8.5E-07	3.6E-08	1.4E-07	--	--
Shop Vac Removal VAI from Top Perimeter Wall Cavities	0	0	2.7E-08	2.0E-07	--	--
Aggregate Risk*	**2.7E-07**	**1.0E-06**	**1.9E-07**	**7.7E-07**	**--**	**--**

Plausible upper-bound means the risk could be considerably lower, even approaching zero.
* Total does not include risk from "Moving Aside - Grace Method," because the higher exposure scenario "Moving Aside VAI – Homeowner Method" was included in the total.

Table V-6. Estimated Plausible Upper-Bound Risks for Contractors for Asbestos and Asbestiform Fibers

Activity	Contractors					
	Worker		Helper		Bystander	
	Typical	High End	Typical	High End	Typical	High End
Based on Lees and Mlynarek						
Moving Boxes	--	--	--	--	--	--
Small Area Clearance	5.9E-08	1.9E-06	4.3E-09	1.4E-07	0	0
Small Area Clearance & Fan Installation	0	0	0	0	0	0
Large Area Clearance	2.0E-08	4.2E-07	3.5E-09	7.4E-08	0	0
Aggregate Risk	**7.9E-08**	**2.3E-06**	**7.8E-09**	**2.1E-07**	**0**	**0**
Based on Claimants' Washington State Study						
Cleaning Stored Items	--	--	--	--	--	--
Ceiling Penetration	1.8E-07	3.2E-06	4.1E-07	7.2E-06	--	--
Moving Aside VAI - Grace Method	6.2E-07	1.3E-05	0	0	--	--
Moving Aside VAI - Homeowner Method	6.8E-07	1.4E-05	1.1E-07	2.4E-06	--	--
Shop Vac Removal VAI from Top Perimeter Wall Cavities	0	0	4.3E-08	1.4E-06	--	--
Aggregate Risk*	**8.6E-07**	**1.8E-05**	**5.7E-07**	**1.1E-05**	**--**	**--**

Plausible upper-bound means the risk could be considerably lower, even approaching zero.
* Total does not include risk from "Moving Aside - Grace Method," because the higher exposure scenario "Moving Aside VAI – Homeowner Method" was included in the total.

Table V-7. Bounding Estimates of Risks for Residents for Asbestiform Fibers and Cleavage Fragments

Activity	Residents					
	Worker		Helper		Bystander	
	Typical	High End	Typical	High End	Typical	High End
Based on Lees and Mlynarek						
Moving Boxes	1.3E-07	6.1E-06	0	0	2.6E-09	2.1E-07
Small Area Clearance	2.2E-07	1.9E-06	1.1E-08	2.0E-07	0	0
Small Area Clearance & Fan Installation	2.5E-07	8.9E-07	8.9E-10	5.9E-09	0	0
Large Area Clearance	7.9E-08	5.4E-07	1.1E-08	6.8E-08	2.5E-10	6.0E-09
Aggregate Risk	**6.8E-07**	**9.4E-06**	**2.3E-08**	**2.7E-07**	**2.8E-09**	**2.1E-07**
Based on Claimants' Washington State Study						
Cleaning Stored Items	0	0	0	0	--	--
Ceiling Penetration	6.1E-07	2.0E-06	7.7E-07	2.6E-06	--	--
Moving Aside VAI - Grace Method	1.7E-06	6.7E-06	0	0	--	--
Moving Aside VAI - Homeowner Method	3.6E-06	1.4E-05	6.6E-07	2.6E-06	--	--
Shop Vac Removal VAI from Top Perimeter Wall Cavities	2.6E-07	1.9E-06	8.1E-08	6.1E-07	--	--
Aggregate Risk*	**4.5E-06**	**1.8E-05**	**1.5E-06**	**5.8E-06**	--	--
Based on Versar/EPA						
Using the Attic with Vermiculite Insulation as a Storage Space	4.3E-07	1.1E-05	--	--	--	--
Wiring or Small Renovation in an Attic Containing Dry Vermiculite	5.5E-07	7.4E-06	--	--	--	--
Removing Vermiculite Attic Insulation	9.2E-07	1.8E-06	--	--	--	--
Aggregate Risk	**1.9E-06**	**2.0E-05**	--	--	--	--

These estimates are upper-end bounding estimates that overestimate the actual risk because cleavage fragments should not be assigned the potency presented in the IRIS file to asbestiform fibers. For example, EPA has recommended that cleavage fragments should not be included when developing risk estimates with the IRIS potency factor (Lioy et al., 2002).

* Total does not include risk from "Moving Aside - Grace Method," because the higher exposure scenario "Moving Aside VAI – Homeowner Method" was included in the total.

Table V-8. Bounding Estimates of Risks for Contractors for Asbestiform Fibers and Cleavage Fragments

Activity	Contractors					
	Worker		Helper		Bystander	
	Typical	High End	Typical	High End	Typical	High End
Based on Lees and Mlynarek						
Moving Boxes	--	--	--	--	--	--
Small Area Clearance	3.5E-07	1.1E-05	1.8E-08	5.7E-07	0	0
Small Area Clearance & Fan Installation	8.0E-07	1.4E-05	2.8E-09	5.0E-08	0	0
Large Area Clearance	2.5E-07	5.3E-06	3.4E-08	7.3E-07	8.0E-10	1.7E-08
Aggregate Risk	**1.4E-06**	**3.1E-05**	**5.5E-08**	**1.3E-06**	**8.0E-10**	**1.7E-08**
Based on Claimants' Washington State Study						
Cleaning Stored Items	--	--	--	--	--	--
Ceiling Penetration	1.9E-06	3.4E-05	2.4E-06	4.3E-05	--	--
Moving Aside VAI - Grace Method	5.4E-06	1.1E-04	0	0	--	--
Moving Aside VAI - Homeowner Method	1.1E-05	2.4E-04	2.1E-06	4.4E-05	--	--
Shop Vac Removal VAI from Top Perimeter Wall Cavities	4.1E-07	1.3E-05	1.3E-07	4.2E-06	--	--
Aggregate Risk*	**1.4E-05**	**2.9E-04**	**4.7E-06**	**9.2E-05**	--	--
Based on Versar/EPA						
Using the Attic with Vermiculite Insulation as a Storage Space	--	--	--	--	--	--
Wiring or Small Renovation in an Attic Containing Dry Vermiculite	5.2E-06	9.3E-05	--	--	--	--
Removing Vermiculite Attic Insulation	2.9E-06	4.6E-05	--	--	--	--
Aggregate Risk	**8.2E-06**	**1.4E-04**	--	--	--	--

These estimates are upper-end bounding estimates that overestimate the actual risk because cleavage fragments should not be assigned the potency presented in the IRIS file for asbestiform fibers. For example, EPA has recommended that cleavage fragments should not be included when developing risk estimates with the IRIS potency factor (Lioy et al., 2002).

* Total does not include risk from "Moving Aside - Grace Method," because the higher exposure scenario "Moving Aside VAI – Homeowner Method" was included in the total.

1. Lees and Mlynarek

For residents, the plausible upper-bound risks for asbestiform fibers were below 10^{-6} (or one in a million). When including cleavage fragments, the bounding aggregate risk estimate for the high-end worker scenario was 9.4×10^{-6}. However, these risks are overestimated because cleavage fragments do not have the same potency as asbestiform fibers, as was assumed for the bounding estimate, and should not be assigned the IRIS potency value for asbestos. Therefore, all of the risks for residents were well within EPA's risk range of 10^{-4} to 10^{-6}, or below, even including cleavage fragments. Given the conservative assumptions made in the estimates, these risks are not a concern.

For contractors, the plausible upper-end risks for asbestiform fibers were above 10^{-6} for only the high-end worker aggregate exposure scenario (9.4×10^{-6}). Even including cleavage fragments, the risks were not above 10^{-4}. Therefore, these risks are not a significant concern.

2. Claimants-Washington

For residents, the plausible upper-bound risks for asbestiform fibers were at or below 10^{-6} for the typical and upper-end scenarios. When including cleavage fragments, the bounding risks range between 10^{-4} and 10^{-6}. However, these risks are overestimated because cleavage fragments do not have the same potency as asbestiform fibers, as was assumed for the bounding estimate, and should not have been included in the asbestos fiber counts. Therefore, these risks for residents were well within EPA's risk range of 10^{-4} to 10^{-6}, even including cleavage fragments. Given the conservative assumptions made in the estimates, these risks are not a significant concern.

For contractors, the plausible upper-end aggregate risks for asbestiform fibers were between 1.8×10^{-5} (worker) and 2.1×10^{-5} (helper). When including cleavage fragments, the bounding risks exceeded 10^{-4} for the worker, but the typical bounding risk estimates were below 10^{-4}. Given the conservative assumptions for exposure duration that were made to develop these estimates and other conservative assumptions, these risks are not a significant concern. The only estimate exceeding 10^{-4} risk was a bounding estimate which included cleavage fragments. Because cleavage fragments should not be

assigned the IRIS cancer potency, this risk estimate represents an extreme bounding estimate.

3. Versar/EPA

For the residents, the bounding risk estimates are between 10^{-4} and 10^{-6}. For the contractor, the high-end aggregate risk marginally exceeded 10^{-4} (1.4×10^{-4}). The Versar study likely included cleavage fragments in the fiber counts, and may have used indirect preparation techniques. Therefore, given the conservative assumptions made in the estimates, these risks are not significant concerns.

4. Libby/EPA

Specific risk estimates were not developed for the Libby/EPA data because it is not clear what activities each sample represents. However, of the 44 personal samples that used direct preparation, the average asbestiform concentration was 0.0093 fibers/cc and the maximum concentration was 0.15 fibers/cc. Only 4 of 44 samples (9%) had detectable fiber concentrations. When including cleavage fragments, the average concentration was 0.12 fibers/cc, and the maximum concentration 0.77 fibers/cc. Only 17 of 44 samples (39%) had detectable concentrations of either asbestiform or cleavage fragments.

These fiber counts are relatively similar to those measured in the other studies, so the Libby/EPA data do not add anything new to the risk calculations that were performed in this study.

C. *When confronted with uncertainties associated in the assessment of risks, assumptions were made that tend towards overestimating the actual risks. Therefore, the true risks are likely lower than estimated in this report.*

The overall approach of the risk assessment was to develop accurate estimates of typical and upper-end risk, but make conservative assumptions (i.e., towards overestimating risk) when confronted by uncertainties. Table V-9 summarizes some of the key areas of uncertainties in the assessment, including an assessment of the directional impact that the assumptions that were made have on the risk assessment.

One of the major areas of uncertainty is the EPA cancer risk factor. This factor was developed from human epidemiologic studies of people that were exposed to high levels of asbestos over prolonged periods. The conservatism of EPA's potency factor is consistent with EPA's approach of developing conservative, health-protective risk factors for use in regulatory settings. However, it is likely that the risk is lower or even zero at the much lower exposure levels that are associated with VAI. Therefore, the use of the EPA cancer risk factor adds significantly to the conservatism of the assessment.

Another uncertainty in the assessment is the exposure frequency and durations. There are no studies or surveys that cataloged data on how often a resident or contractor may engage in activities that disturb VAI and for how long. Therefore, this assessment makes conservative assumptions regarding exposure durations that tend to overestimate risks.

Risks were calculated for exposure data from several studies. It is important to note that the data that included cleavage fragments represents overestimates of the exposure to asbestiform fibers of the type that are known to cause cancer at high dosages. In particular, the fiber counts in Versar/EPA study likely include cleavage fragments, which limit the applicability of these data to risk estimates as screening level estimates. This means that if the risk estimates are low, as they are, then the actual risks are expected to be even lower. Screening-level estimates are typically used for screening out those risks which may require further study from risks that are low even using high-end conservative data and assumptions, where no further study is necessary.

Table V-9. Summary of Potential Uncertainties in the Risk Assessment

Element of Risk Assessment	Risk Assessment Factor	Description	Directional Impact on Risk Estimates
Exposure Assessment	Exposure Duration Assumptions	For both residents and contractors, typical and upper-bound exposure durations were developed. The upper-bound durations are designed to represent the individuals or contractors that may spend the most time in areas with VAI exposure. Because of the uncertainty in developing these estimates, conservative assumptions were made that would tend to overpredict the likely exposure durations of most individuals.	↑
	Lees and Mlynarek fiber counts	These fiber counts were collected with the most appropriate methods for risk assessment, and are likely the most accurate.	↔
	Versar/EPA fiber counts	The fiber counts did not match the PCME definition. It is not clear if fibers under 0.4 μm in diameter were excluded or if cleavage fragments were included. Also, indirect preparation techniques were apparently used. All these factors would result in an overestimate of fiber counts.	↑
	Claimants-Washington fiber counts	The fiber counts in the claimants' expert report did not match the PCME definition. However, Dr. Lee was able to develop PCME estimates based on the count sheets, but with some uncertainties.	↔

Element of Risk Assessment	Risk Assessment Factor	Description	Directional Impact on Risk Estimates
	Libby/EPA fiber counts	Although Dr. Lee was able to develop PCME estimates from the Libby data, the measurement methods, the circumstances in which the data were collected, and quality control was poor, which creates uncertainties in any risk estimates.	↔
Risk Estimates	EPA/IRIS cancer risk factor	The EPA cancer risk factor is a conservative, upper-bound estimate of risk. The factor assumes a linear, no-threshold model, which means that risks at low doses are assumed to be proportional with dosage to risks at high doses. It is possible that there is a threshold below which there is no risk, or that the risk at lower dosages (such as observed for VAI) is lower than represented by the EPA risk factor.	↑
	Separate risk estimates with cleavage fragments	To be conservative (i.e., tend to overestimate risks), risk estimates were calculated including cleavage fragments, in addition to estimates with only asbestiform fibers. As Dr. Ilgren has certified, cleavage fragments are not carcinogenic. The IRIS risk factors were developed from studies in environments without a significant amount of cleavage fragments, so using the IRIS risk factor with fiber counts that included cleavage fragments will result in an overestimate of risk. The IRIS file for asbestos says that only asbestos and asbestiform fibers should be counted.	↑

Element of Risk Assessment	Risk Assessment Factor	Description	Directional Impact on Risk Estimates
Risk Characterization	Versar/EPA Risk Estimates	The fiber counts in the Versar study are likely overestimates of PCME concentrations, because cleavage fragments may have been included and indirect preparation techniques may have been used. Thus, the risks estimated with these fiber counts are likely to be overestimates. Additionally, the Versar/EPA assessment used the EPA/IRIS cancer risk factor, which may overestimate risk at the exposure levels in the study (see above).	↑

D. *There are other studies that provide information on the asbestos risks associated with VAI that show that the risks are low.*

1. <u>The Versar/EPA study found that the risks for residents with VAI in their homes are low.</u>

This report presents risk estimates based on the Versar/EPA study data. However, the draft Versar/EPA report also presented risk estimates for residents (but not contractors), using some different exposure duration assumptions than employed in this report. The risks presented in the Versar/EPA report are very low. Most of the risk estimates are below 10^{-6} (or one in a million). There were a handful of risk estimates between 10^{-4} and 10^{-6}, but none above 10^{-4}.

I provided peer review comments on this report (Anderson, 2002) and noted the low risks despite the general tendency in the study to overestimate risks, because of the method used for the fiber counts (discussed in detail earlier) and the some of the exposure duration assumptions.

The highest risk found by Versar/EPA was $1.5\text{x}10^{-5}$ for a person living in a home where minimal vermiculite attic insulation disturbance occurs four times per year. However, I noted in my review that this risk was inappropriately estimated. The intention of the scenario was to estimate the risk to a resident in a living space in the period during a disturbance in the attic from an activity such as moving boxes. However, there were no fibers found in the measurement made in the living space. Therefore, the risk should have appropriately been described as zero. Instead, the study authors used the fiber count result from the attic, thus assuming that the resident lives in the attic, and pointed out that the risk was overestimated. However, as stated in the report, this risk estimate is highly misleading, and would have more appropriately been listed as zero.

2. <u>The ATSDR medical monitoring study in Libby, Montana showed that exposure to VAI was not associated with any health effects.</u>

Further evidence for the low risk associated with vermiculite attic insulation can be found in the medical monitoring study in Libby conducted by the

ATSDR (ATSDR, 2001). In this study, ATSDR conducted chest radiographs and spirometry testing on a subpopulation of Libby residents that included 6,149 current or former residents of Libby and the surrounding area. The study also included a questionnaire about potential exposure pathways for each resident. There were two relevant pathways to this analysis: (1) having vermiculite insulation in homes (termed *Vermins* in study report), and (2) handling vermiculite insulation (termed *Vermhand*).

ATSDR conducted a multivariate logistic regression analysis to determine which exposure pathways were associated with pleural abnormalities (see Table 12 of the ATSDR report). The regression included 18 exposure categories and made statistical adjustments for age, sex, body mass index, cigarette smoking status, years lived in the Libby area, neighborhood environmental concern level, and pulmonary disease or pulmonary surgery. Neither the *Vermins* nor *Vermhand* exposure pathways were statistically significant in the model, indicating that these pathways were not associated with pleural abnormalities of the lung. This means that there was no evidence in the lung tests that exposure to VAI was associated with exposure to asbestos. Therefore, these results provide further evidence that the cancer risks are low.

ATSDR also conducted a similar logistic regression analysis for the restrictive abnormalities identified in the pulmonary function tests. Again, the analysis showed that the *Vermins* and *Vermhand* exposure pathways were not associated with any abnormalities.

Dr. Gary Marsh, a Professor of Biostatistics at University of Pittsburgh Graduate School of Public Health, reviewed the ATSDR study and also found that the study provided no evidence to show that the living in a home containing Zonolite insulation is associated with an elevated health risk (Marsh, 2002).

VI. The asbestos risks associated with exposure to VAI can be characterized relative to appropriate regulatory criteria.

A. Compared to relevant regulatory criteria, the asbestos risks associated with contact with VAI are low and not of significant concern.

The most accurate risk estimates are without cleavage fragments, as recommended by EPA (Lioy et al., 2002). The estimated risks for residents were very low, at or below 10^{-6}, and well within or below EPA's recommended risk range.

For contractors, the risks were higher than residents because the assumed exposure frequency and durations were higher. However, when making reasonable assumptions, the estimated risks were within ranges considered acceptable by EPA, and lower than many other occupational risks. The risks are considerably lower than the risks for workers exposed at the OSHA PEL. For example, at the current PEL, OSHA estimates that a worker exposed for 45 years would have a risk of 3.4 per 1000 (or 3.4×10^{-3}). The risks to workers associated with VAI are much lower.

B. Compared to other risks to which people are routinely exposed, the risks associated with asbestos exposure to VAI are low.

When characterizing risk estimates, it must be understood that risk is a fact of everyday life. As an example, Figure VI-1 displays the lifetime risks of dying from a variety of causes. The risks are highest for heart disease and cancer (all causes) at 18% and 14%, respectively. The upper and lower ends of EPA's acceptable risk range are shown at the right end of the figure. The upper end is at 10^{-4} (or 0.01%) risk and the lower end is at 10^{-6} (or 0.0001%) risk. The risk of dying by being struck by lighting is an example of a risk within EPA's acceptable risk range at 0.002%. However, the risks of dying from a bicycle accident, a fire, drowning, food poisoning, homicide, and others are greater than EPA's upper risk value of 0.01%. These show that people live with and accept greater risks than are considered acceptable for environmental exposures by regulatory authorities such as EPA.

In addition to the risks displayed in Figure IV-1, it is also worth noting that there are many environmental risks that are similar to or higher than the risks estimated for VAI. For example, Figure IV-2 shows the average cancer risks associated

with air pollutants in urban and rural counties estimated from EPA's National Air Toxics Assessment (NATA). The risks range from 10^{-4} to 10^{-5}, and are experienced by most Americans simply by walking outside or breathing air inside their homes that has infiltrated inside from the outdoor air. This is in contrast to the air pollution risk that may exist for residences that live near an industrial facility, which are often even higher.

Another environmental example is the risks associated with carcinogens in drinking water. Table IV-1 displays the risk estimates at the Maximum Contaminant Level (MCL) for five chemicals. The MCL is set by EPA as an acceptable risk level for drinking water. The risks are generally in the 10^{-4} to 10^{-6} range, consistent with EPA's acceptable risk range.

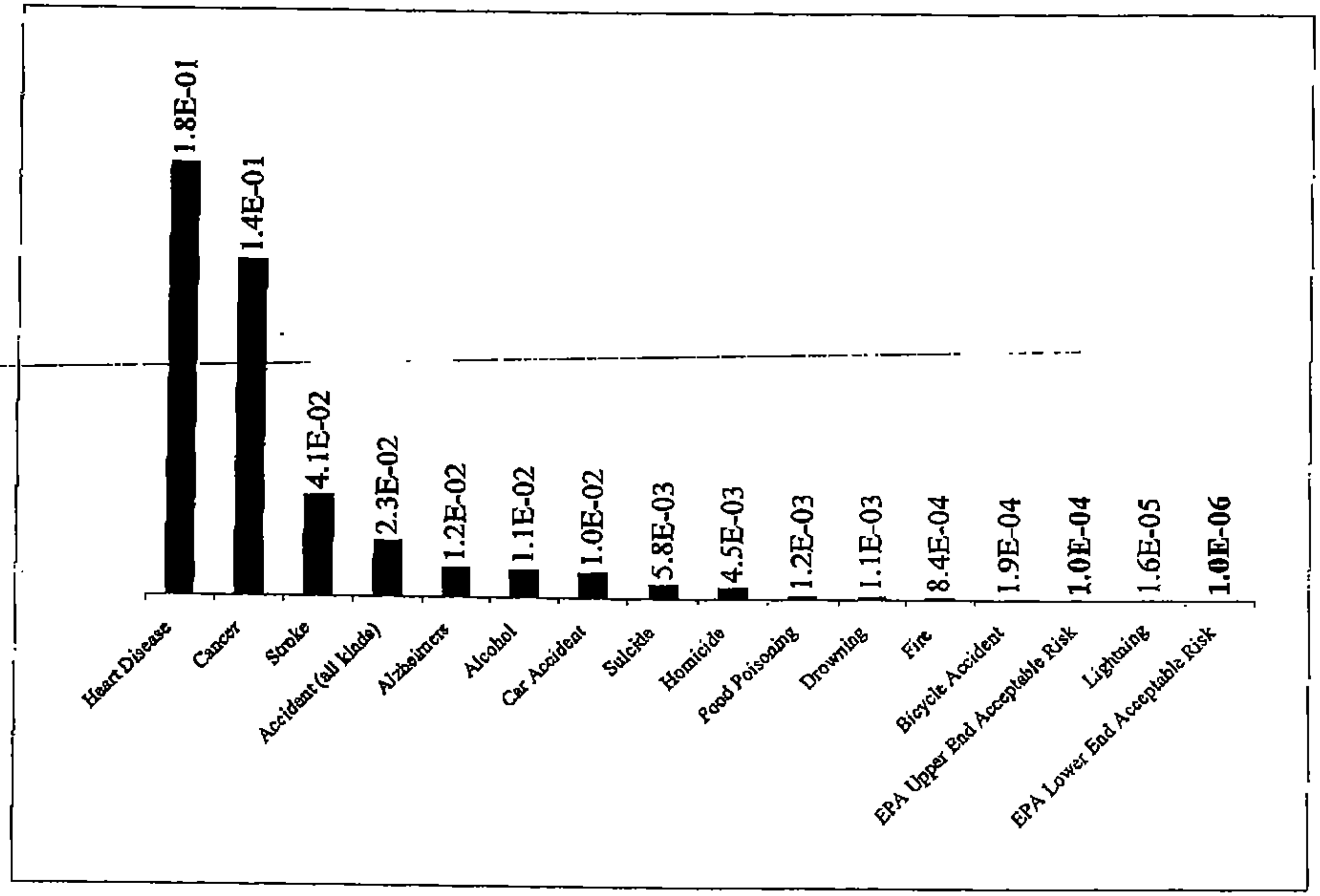
These examples show that the estimated risks associated with VAI are similar or less than risks for common activities in everyday life, and similar to or less than risks of breathing ambient air or drinking tap water.

Table VI-1. Summary of Drinking Water Cancer Risks at the Maximum Contaminant Level Set by EPA

Chemical	MCL	Cancer Slope Factor	Drinking Water Unit Risk	Risk @ MCL, intake 2L/day, 70 kg bw, lifetime exposure
Arsenic	0.010 mg/L *	1.5 per (mg/kg)/day	5×10^{-5} per (µg/L)	**4.30E-04**
Benzene	0.005 mg/L	1.5×10^{-2} to 5.5×10^{-2} per (mg/kg)/day	4.4×10^{-4} to 1.6×10^{-3} per (mg/L)	**2.14E-06** **7.85E-06**
Carbon Tetrachloride	0.005 mg/L	1.3×10^{-1} per (mg/kg)/day	3.7×10^{-6} per (µg/L)	**1.85E-05**
1,2-Dichloroethane	0.005 mg/L	9.1×10^{-2} per (mg/kg)/day	2.6×10^{-6} per (µg/L)	**1.30E-05**
Vinyl chloride	0.002 mg/L			
Continuous lifetime exposure adulthood				
	LMS method	7.2×10^{-1} per (mg/kg)/day	2.1×10^{-5} per (µg/L)	**4.11E-05**
	LED 10/Linear	7.5×10^{-1} per (mg/kg)/day	2.1×10^{-5} per (µg/L)	**4.28E-05**
Continuous lifetime exposure birth				
	LMS method	1.4 per (mg/kg)/day	4.2×10^{-5} per (µg/L)	**8.00E-05**
	LED 10/Linear	1.5 per (mg/kg)/day	4.2×10^{-5} per (µg/L)	**8.57E-05**

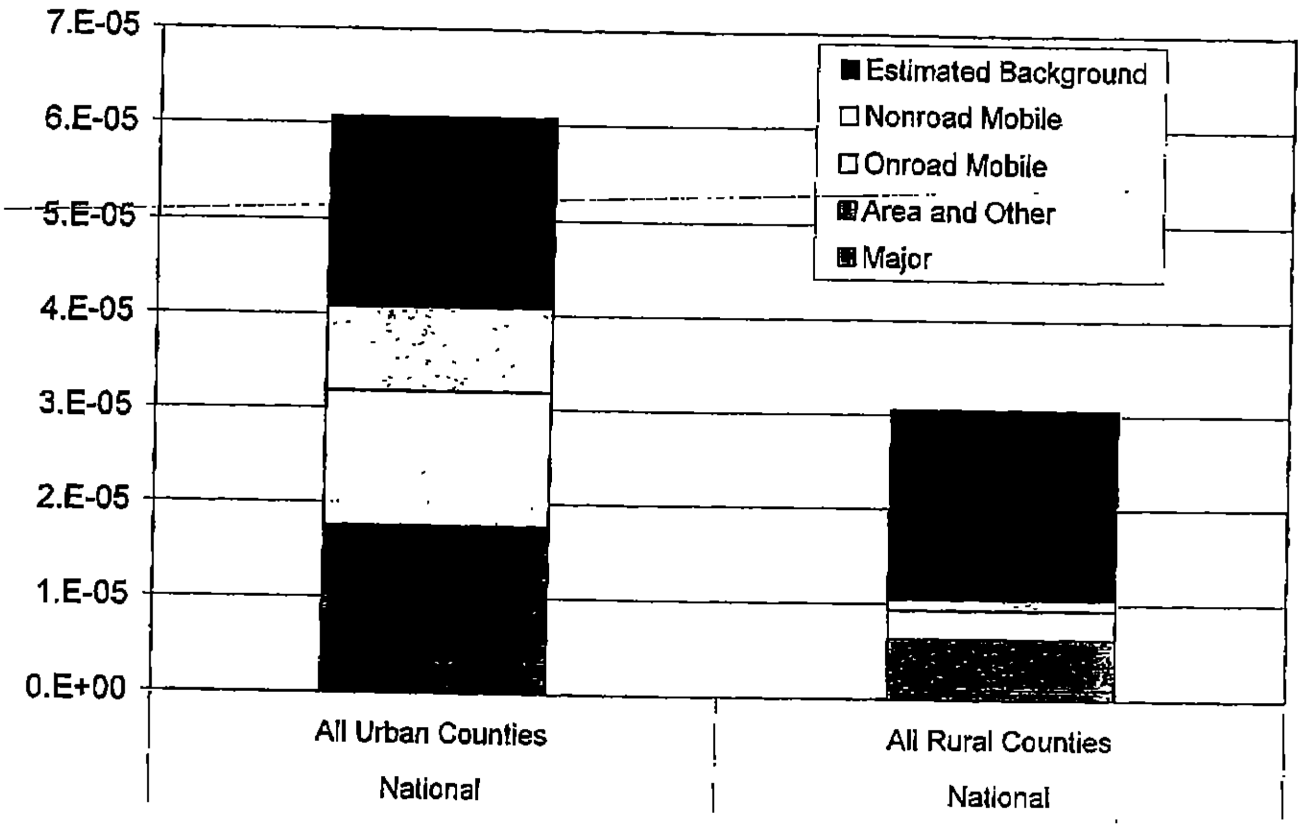
* MCL as of 01/23/06

Figure VI-1. Summary of Estimated Lifetime Mortality Risks for Various Causes



Note: The values in this figure were adapted from data on the Harvard Center for Risk Analysis website: http://www.hcra.harvard.edu/. The risks on the website are on an annual basis, and were multiplied by 70 years to estimate lifetime risks.

Figure VI-2. Summary of Estimated Cancer Risks from Air Pollutants from EPA's National Air Toxics Assessment



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The foregoing represents my opinion to a reasonable degree of scientific certainty.

Date: April 14, 2003

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